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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, ex rel. LAURIE SIMPSON, *Plaintiff*, v. BAYER CORPORATION, et al., *Defendants*.	Hon. Jose L. Linares *Civil Action No.* 05-3895 **UNITED STATES' STATEMENT OF INTEREST**

The United States submits this Statement of Interest to address the Defendants' argument that a pharmaceutical company cannot be held liable under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 et seq., for paying kickbacks to induce doctors to use a drug and for causing the submissions of claims for non-covered uses of a drug, merely because the Government pays for the drug through "bundled" payments to hospitals. If accepted, the Defendants' argument would transform an initiative to curb health care costs into a green light for companies to

engage in fraudulent activity that would exacerbate such costs.

As explained below, when a company causes a hospital to misrepresent that claims complied with material requirements for payment relating to a drug, and the company acts knowingly within the meaning of the FCA, there is potential liability under the FCA, regardless whether the Government paid for the drug as an individual item or, as here, through a flat payment for a bundle of goods and services. Put differently, the mechanics of payment (the fact that the Government reimburses through a bundled payment) does not bar the Government from enforcing the Anti-Kickback Statute ("AKS") and drug coverage requirements with respect to a drug in that bundle.

The Defendants base their argument on a line of cases that pre-dates the Supreme Court's decision in Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016) ("Escobar"). They argue that because the Government paid for the drug Trasylol through a flat, bundled payment, any underlying violations could not have increased the amount the Government paid and therefore could not be material to the Government's decision to pay the claim. Under the Defendants' theory, even if a pharmaceutical company gave a doctor an envelope stuffed with cash as a kickback to use a drug that is paid for through a bundled payment, the company could not be liable under the FCA due to the absence of materiality.

These cases, however, provide no support for the Defendants' argument because the materiality inquiry under Escobar focuses on the Government's decision to pay, not the payment amount, and because these pre-Escobar cases did not apply the materiality test as articulated by the Supreme Court. The Defendants' argument about increased costs goes to the question of damages, which is wholly separate from the threshold issues of materiality and liability.

The Government takes no position on the merits of the Relator's case; it submits this Statement of Interest solely to address this point of law. The FCA is the federal Government's primary tool to combat fraud and recover losses due to fraud in federal programs. The United States therefore has a substantial interest in the way that courts interpret the FCA and the statutes and regulations governing the public health insurance programs.

I. Background

The Government reimburses hospitals for items and services provided to Medicare beneficiaries during inpatient stays and outpatient encounters via flat, bundled payments. See 42 U.S.C. §§ 1395l(t), 1395ww(d). When Congress created the bundled payment system, the Government stopped paying for each item or service separately, on a cost basis; instead, it began paying for items and services in aggregated payments based on the average cost of caring for similar patients in similar circumstances – thereby creating incentives for providers to

economize on the cost of care. See Appalachian Reg'l Healthcare, Inc. v. Shalala, 131 F.3d 1050, 1051 & n.1 (D.C. Cir. 1997).

The amount of the bundled payment is based on the specific category into which the inpatient stay or outpatient encounter falls. In turn, the category depends on the characteristics of the patient, his or her conditions, and some (but not necessarily all) of the treatment given to the patient. See 42 C.F.R. §§ 412.60, 419.31. Generally, each inpatient stay or outpatient encounter that falls into a given category is reimbursed by Medicare at the same flat rate – even if care provided to a particular patient involves more or less (or more or less costly) treatment than is typical.[1] Id. §§ 412.1, 419.2.

II. Bundled Payment Systems do Not Preclude False Claims Act Liability for Claims Tainted by Kickbacks or Violations of Drug Coverage Requirements.

The materiality inquiry under the FCA focuses on the likely effect on the

[1] Even within bundled payment systems, the actual care provided may be relevant to the size of payment: First, drug use or non-use may contribute to the category into which the inpatient stay or outpatient encounter falls in certain cases. Second, where providers' actual costs exceed a certain threshold, Medicare pays for some of the excess through outlier payments. See 42 U.S.C. §§ 1395l(t)(5), 1395ww(d)(5)(A). Third, certain new drugs in the first several years of their use may be paid for via add-on or pass-through payments that compensate providers based in part on the actual cost of the drug over and above the bundled rate payment. See id. §§ 1395l(t)(6), 1395ww(d)(5)(K). And fourth, for inpatient stays, "critical access hospitals" in rural areas are reimbursed partly based on the actual cost of the items and services provided to beneficiaries. See id. § 1395m(g)(1).

Government's decision to pay were it to know about a defendant's non-compliance with certain requirements. Compliance with the AKS and drug coverage rules are both material to such payment decisions. This is true regardless of the manner by which the Government chooses to pay for goods and services, whether separately or through bundled payments.

a. Under Escobar, the focus of the materiality inquiry is on whether a misrepresentation is "capable of influencing" the Government's payment decision.

False claims must be "material" to the Government's decision to pay in order to provide a basis for liability under the FCA. The FCA defines the term "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). In Escobar, the Supreme Court stressed that this definition was the same as that employed in "other federal fraud statutes," which "descends from 'common-law antecedents.'" Escobar, 136 S. Ct. at 2002. The Court explained that the same basic concept of materiality applies in all of these contexts and focuses upon "the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." Id. (quoting 26 RICHARD LORD, WILLISTON ON CONTRACTS § 69:12, at 549 (4th ed. 2003)). The Court stated that "a matter is material" if: (1) a reasonable person would attach importance to it in determining a "choice of action," or (2) "the defendant knew or had reason to know that the recipient of the

representation attaches importance to the specific matter in 'determining his choice of action,'" regardless of whether a reasonable person would do so. Id. at 2002-03.

While drawing on numerous fraud statutes, Escobar framed the test of materiality under the FCA in terms of the likely effect on the Government's decision to pay in whole or in part when the Government has actual knowledge of non-compliance with a particular requirement. See id. at 2003 (stating that proof of materiality can include whether Government consistently "refuses to pay claims" or "pays a particular claim in full").

The Court clarified that a variety of factors are relevant to the materiality inquiry and stressed that no one factor is automatically dispositive. Id. at 2001 (citing Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 39 (2011)). The Court observed that the materiality inquiry may consider whether the Government took action when it had actual knowledge of similar violations, id. at 2003-04; whether the violation goes to the "essence of the bargain," id. at 2003 n.5 (quoting Junius Constr. Co. v. Cohen, 178 N.E. 672, 674 (N.Y. 1931)); and whether the violation is significant or "minor or insubstantial[.]," id. at 2003. The Court also explained that designation of a particular statutory, regulatory, or contractual requirement as a condition of payment is relevant to the materiality inquiry, but it rejected the notion that the designation could be "automatically dispositive" as a matter of law. Id. The Court's fact-based approach to materiality thus requires courts to view

materiality holistically and practically, rather than as being dictated by formal designations.

b. Misrepresentations that are material remain material regardless of whether the claim is reimbursed through a bundled payment.

As an initial matter, it is beyond dispute that, as a general proposition, misrepresentations of compliance with the AKS render claims materially false. The AKS prohibits paying any remuneration to induce the use of a medical item or service for which reimbursement may be sought from federal programs. 42 U.S.C. § 1320a-7b. Compliance with the AKS goes to the heart of what the Government pays for when it subsidizes health care: the assurance that care is being provided based on professional medical judgment, rather than on a provider's personal financial interest. A kickback wholly undermines this assurance.

Likewise, it is undisputed that, as a general proposition, misrepresentations of compliance with drug coverage requirements render a claim for reimbursement materially false. Congress has established that, if a provider's use of a medical item or service is not covered by Medicare or other federal programs, a claim for payment for that item or service is not reimbursable. See, e.g., 42 U.S.C. § 1395y(a) (providing that, with exceptions not relevant here, Medicare will not pay for items and services not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member").

Contrary to the Defendants' argument, violations of the AKS or coverage

rules are not rendered immaterial merely because the Government's reimbursement mechanism pays certain claims through bundled payments rather than per item.

Bundled payments are made "in full satisfaction of the bundle of covered items and services provided during a single inpatient hospital stay." Appalachian Reg'l, 131 F.3d at 1053. A bundled payment "is certainly in some sense payment for each of the individual items or services that compose the bundle." Id. Because a bundled payment constitutes payment for the individual items and services that "compose the bundle," id., the Government may enforce any material requirement that is applicable to those items and services. The fact that payments are made in a bundle, as opposed to on an item-by-item basis, does not render compliance with these requirements any less material.

The First Circuit affirmed this point in U.S. ex rel. Hutcheson v. Blackstone Med., 647 F.3d 377, 394 (1st Cir. 2011), where it held that misrepresentations in hospital claims could be capable of influencing Medicare's decision to pay the claims. In Hutcheson, a relator alleged that a medical device maker paid kickbacks to induce doctors to use its device in surgeries. Id. at 378. In affirming the district court's denial of the defendant's motion to dismiss, the First Circuit reasoned that the defendant's argument that Medicare "would excuse these violations [of material requirements regarding items or services] because of a bureaucratic [bundled payment] mechanism. . . . impermissibly cabins what the government

may consider material." Id. at 394-95. Hutcheson stands for the proposition that misrepresentations about kickbacks and other violations are capable of influencing the Government's decision whether to pay claims regardless of its reimbursement mechanism.

For these reasons, the Court should reject the Defendants' argument that otherwise material requirements somehow become immaterial because the Government's use of a bundled payment could not have increased its costs. See Defs. Mem. Opp. Summ. J. at 11. In fact, nothing in either the FCA or Escobar supports the Defendants' narrow view of materiality. Materiality focuses on how a misrepresentation affects the decision to pay, not whether the Government incurred increased costs, as Defendants argue. See 31 U.S.C. § 3729(b)(4). Whether the Government incurred increased costs goes to damages, which is a separate question.

Finding no support in Escobar itself, the Defendants rely on a line of cases that pre-dates Escobar. Many of these cases do not even involve the AKS or drug coverage requirements. These pre-Escobar cases evaluated materiality by looking at whether the conduct at issue increased the Government's costs. See U.S. ex rel. Zemplenyi v. Group Health Cooperative, No. 09-603, 2011 WL 814261, at *2 (W.D. Wash. Mar. 3, 2011) (medically unnecessary surgeries did not increase Government's costs); U.S. ex rel. Wageman v. Doctor's Hosp. of Slidell, No. 09-

3506, 2010 WL 3168087, at *7 (E.D. La. Aug. 6, 2010) (altering patient records to extend hospital stays did not increase Government's costs); U.S. ex rel. Stephens v. Tissue Sci. Lab., Inc., 664 F.Supp.2d 1310, 1318 (N.D. Ga. 2009) (off-label uses of drug did not increase Government's costs); U.S. ex rel. Kennedy v. Aventis Pharm. Inc., No. 03-2750, 2008 WL 5211021, at *3 (N.D. Ill. Dec. 10, 2008) (same); U.S. ex rel. Digiovanni v. St. Joseph's/Candler Health Sys., Inc., No. 404-190, 2008 WL 395012, at *6 (S.D. Ga. Feb. 8, 2008) (billing for equipment that was re-used did not increase Government's costs); U.S. ex rel. Schell v. Battle Creek Health Sys., No. 1-143, 2004 WL 784978, at *4 (W.D. Mich. Feb. 25, 2004) (billing for multi-dose vial but using only single dose did not increase Government's costs).[2] This method of evaluating materiality is incompatible with Escobar, which focuses on how the misrepresentation affects the Government's payment decision rather than how it affects the payment amount.

The only post-Escobar case that the Defendants cite, In re Plavix Mktg., Sales Practice and Prod. Liab. Litig. (No. II), also provides no support for their position. In Plavix, the relator alleged that the drug Plavix was included on certain state formularies and that Medicaid therefore "automatically" reimbursed claims

[2] Another case that the Defendants cite, U.S. ex rel. Portilla v. Riverview Post Acute Care Ctr., did not even address materiality in the context of a bundled payment, instead dismissing this claim on FED. R. CIV. P. 9(b) grounds. No. 12-1842, 2014 WL 1293882 (D.N.J. Mar. 31, 2014).

for the drug even though the defendants had falsely certified that the drug was cost-effective. No. 13-1039, 2017 WL 2780744, at *13-14 (D.N.J. June 27, 2017). The district court held that because the relator herself had pled that the Government "automatically" paid claims solely because Plavix was included on state formularies – and nothing more – she had failed to, and could not, plead materiality. Id. at *14. By alleging (erroneously) that the Government's decision to pay was based solely on a factor unconnected to the defendant's alleged wrongdoing, the relator failed to plead that the defendant's misconduct had any likely effect on its payment. See Escobar, 136 S. Ct. at 2002-03. This case-specific pleading deficiency does not support the sweeping argument advanced by the Defendants that bundled payments automatically provide defendants broad immunity from FCA liability.

Nor does the Defendants' increased-cost theory of materiality find support in the Third Circuit's Hutchins decision. See Defs. Mem. Opp. Summ. J. at 11 (citing Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176 (3d Cir. 2001)). Although the Defendants seize on language in Hutchins about "financial loss," that case is easily distinguishable. In Hutchins, the issue was whether a law firm's submission to a bankruptcy court of inflated legal bills solely for the court's approval constituted "a false claim for payment or approval" under the FCA. Hutchins, 253 F.3d at 182. The relator himself conceded that "no claim [was] made against

United States Treasury money"; rather, his theory was that the mere submission of the legal bills for approval amounted to false claims. Id. The Third Circuit held that claims that "do not or would not cause financial loss to the government" are not false claims. Id. at 184. In short, the Third Circuit simply held that a "claim" requires a demand on the public fisc, i.e., Government money, as opposed to money that is or never was the property of the Government. Id.[3]; see also United States ex rel. Hayes v. CMC Elecs., 297 F. Supp. 2d 734, 738-39 (D.N.J. 2003).

The Defendants claim that allowing liability in the context of a bundled payment mechanism leads to "absurd" results because a defendant could be held liable any time a hospital submitted a claim for inpatient reimbursement that included any non-compliant item or when it failed to comply with any requirement, no matter how marginal. Defs. Mem. Supp. Summ. J. at 17. But just as the existence of a bundled payment does not eliminate what could be an otherwise material violation, it does not create a material violation where one would not otherwise exist. In all cases, the inquiry under Escobar remains the same: whether the defendant's violation will likely affect the Government's payment decision under the factors identified in the decision.

[3] The FCA was amended to revise the definition of "claim" that was at issue in Hutchins. The amended definition of "claim" now includes demands for payment, whether or not the United States has title to the money, as long as other conditions are met. 31 U.S.C § 3730(b)(2).

Generally, deficiencies in goods and services or non-compliance with requirements that are directly related to the medical care provided and the reason why the patient is in the hospital in the first place, are likely to be important to the Government's payment decision. Thus, a reasonable person likely would attach importance to unapproved and unsafe uses of a drug during surgery or the payment of kickbacks, which may compromise medical judgment. That does not mean that a person would attach similar importance to fraudulently obtained light bulbs, to use the "absurd" example offered by the Defendants.

In fact, the only "absurd" result would be the type of per se rule that the Defendants seek. If accepted, the Defendants' argument would mean that the Government could never recover when kickbacks or drug coverage violations occur in the context of inpatient hospital stays. This would effectively insulate the pharmaceutical industry from any liability under the FCA in connection with fraudulent conduct underlying the billions of dollars the Government pays each year for inpatient hospital stays through Medicare Part A.

c. Because a claim does not have to be false on its face to trigger liability, the Court should reject Defendants' argument that they are not liable because the claims did not identify Trasylol.

Aside from materiality, the Defendants also cannot escape liability under the FCA merely because the claims may not have explicitly stated that Trasylol was used in the surgeries. See Defs. Mem. Supp. Summ. J. at 15.

As an initial matter, the Escobar Court rejected overly rigid notions of falsity in FCA matters by specifically upholding implied false certification liability. The Court held that a claim may be false when specific representations on the claim omit that there were violations of statutory, regulatory, or contractual requirements, if those omissions render the representations misleading. Escobar, 136 S. Ct. at 1999; see also U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 306 (3d Cir. 2011) (recognizing the implied false certification theory of liability). Put differently, omissions are at the heart of the implied false certification theory of liability. Accordingly, the Defendants can be liable for causing hospitals to submit claims for inpatient stays that the hospitals implicitly represented complied with statutory requirements, even absent any mention of those requirements on the face of the claim.

The Defendants claim, incorrectly, that the implied false certification theory requires that a claim make "specific representations about the goods or services provided," and, based on that false premise, they contend that, because there are no separate claims for Trasylol, there can be no specific representations as to Trasylol. See Defs. Mem. Supp. Summ. J. at 17.

This argument misreads Escobar, which expressly declined to decide whether a defendant could be liable under an implied false certification theory in the absence of a specific representation. See Escobar, 136 S. Ct. at 2000

(explaining that since the claims in that case "do more than merely demand payment," the Court "need not resolve whether all claims for payment implicitly represent that the billing party is legally entitled to payment") (emphasis added). Escobar therefore left intact the Third Circuit's holding in Wilkins adopting the implied false certification theory of liability without requiring a specific representation. See Wilkins, 659 F.3d at 306.

Moreover, a claim for hospital inpatient services constitutes both a specific representation about the particular bundle of services provided and an implicit representation that the patient received the goods and services that were reasonable and necessary for his or her treatment in the hospital. The fact that the claims did not mention Trasylol itself is unsurprising because the claims were not for a "surgery" per se but for all of the goods and services provided to the patient at the hospital. See 42 C.F.R. § 412.60 (Diagnosis Related Groups are based on, among other things, "procedures performed" in the hospital). Indeed, that is the whole point of a bundled payment – it covers not only the surgery but all of the goods and services provided during an inpatient stay – including, here, Trasylol. If the claims were just for the surgery, as the Defendants frame it, then the hospitals would need to submit separate claims for all of the other things – such as Trasylol – that are provided to the patient while in the hospital. Instead, because the claim covers everything, it does not need to specifically identify Trasylol in order for it to

constitute a claim for Trasylol. See Appalachian Reg'l, 131 F.3d at 1053 (holding that bundled payment "is certainly in some sense payment for each of the individual items or services that compose the bundle").

* * *

Congress established bundled payment mechanisms to control health care costs. The Defendants' effort to insulate themselves from civil liability under the FCA transforms this cost-control program into permission to engage in fraud in connection with the provision of goods and services that comprise that bundle. The Court should hold that material violations remain material regardless of whether the Government pays the claims through a bundled payment.

Dated: December 11, 2018
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Respectfully submitted,

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CERTIFICATE OF SERVICE

Re: *United States ex rel. Simpson v. Bayer Corporation, et al.*
Civil Action No. 05-3895

I, Assistant U.S. Attorney Charles Graybow, hereby certify that on December 11, 2018, I caused a copy of the United States' Statement of Interest, in the above-referenced matter, to be served on the following, pursuant to the United States District Court, District of New Jersey, Electronic Case Filing Policies and Procedures § 14(b)(1) (amended September 1, 2008):

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I certify under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: December 11, 2018
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